COMMITTEE ON LEGISLATIVE RESEARCH OVERSIGHT DIVISION

FISCAL NOTE

<u>L.R. No.</u>: 4623-01 <u>Bill No.</u>: HB 1952

Subject: Health Care; Insurance - Medical; Medical Procedures and Personnel

<u>Type</u>: Original

<u>Date</u>: March 25, 2002

FISCAL SUMMARY

ESTIMATED NET EFFECT ON STATE FUNDS				
FUND AFFECTED	FY 2003	FY 2004	FY 2005	
All funds	(Unknown)	(Unknown)	(Unknown)	
Conservation	(Unknown)	(Unknown)	(Unknown)	
Insurance Dedicated	\$9,850	\$0	\$0	
Highway	(Unknown)	(Unknown)	(Unknown)	
Total Estimated Net Effect on <u>All</u> State Funds	(Unknown)	(Unknown)	(Unknown)	

ESTIMATED NET EFFECT ON FEDERAL FUNDS				
FUND AFFECTED	FY 2003	FY 2004	FY 2005	
Total Estimated Net Effect on <u>All</u> Federal Funds	\$0	\$0	\$0	

ESTIMATED NET EFFECT ON LOCAL FUNDS				
FUND AFFECTED	FY 2003	FY 2004	FY 2005	
Local Government	(Unknown)	(Unknown)	(Unknown)	

Numbers within parentheses: () indicate costs or losses.

This fiscal note contains 5 pages.

FISCAL ANALYSIS

<u>ASSUMPTION</u>

Officials from the **Department of Insurance (INS)** assume insurers and HMOs would be required to amend their policies to comply with this legislation. Amendments must be filed with INS. INS estimates that 171 insurers and 26 HMOs would be required to file at least one amendment to their policy form with a filing fee of \$50, resulting in revenue of \$9,850 in FY 2003. INS has reached capacity in policy form reviews and the additional workload created by this legislation would cause delays in policy form reviews. Additional staff are not being requested with this single proposal, but if multiple proposals pass during the legislative session which require policy form amendments, the department would need to request additional staff to handle the increase in workload.

Officials from the **Department of Social Services - Division of Medical Services (DMS)** assume there will not be a fiscal impact to the DMS from this proposed legislation. Section 376.429.9 exempts Title XIX of the Social Security Act from the provisions of this legislation. However, Title XXI (States Children's Health Insurance Program - SCHIP) is not included in the programs that are exempt. DMS states in Missouri, the Title XXI program is administered through the Title XIX program therefore, the DMS assumes the Title XXI program is also exempt from this proposed legislation.

Officials from the **Missouri Department of Conservation (MDC)** state that this proposal mandates insurance coverage for clinical trials for treatment of cancer and other life-threatening illnesses. MDC assumes this proposed legislation has a unknown fiscal impact on MDC funds.

Officials from **Missouri Consolidated Health Care Plan (HCP)** assume that requiring the medical plan to cover Phase I, Phase III or Phase IV clinical trials for cancer and other life threatening conditions could result in an increase in the plan's financial risk. Since the treatments may vary and only a few providers would be able to administer the treatments, the cost could be significant. HCP states to reduce this risk, the plan may transfer these additional costs to the members through an increase of premiums. Since the type of treatments, the associated costs and the number of patients cannot be estimated, the overall cost is unknown but could be significant. **Oversight** assumes unknown costs to the Public Entities, also.

HCP states the proposal does include an exclusion for "items and services customarily provided by the research sponsors free of charge for any enrollee in the trial". However, if health plans are required to cover the routine patient care costs incurred for drugs and devices that have been approved by the FDA, the sponsors of such programs may cut the funding to these programs and rely on the health plans' reimbursement for funding. Again, should this occur, the plans may transfer the additional costs to the members through increased premiums.

ASSUMPTION (continued)

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Officials from the **Department of Public Safety - Missouri State Highway Patrol** defer their fiscal note response to the Department of Transportation.

Officials from the **Department of Transportation (DHT)** assume this legislation requires coverage for certain patient care costs for certain clinical trials. This legislation will have no fiscal impact on DHT. The Highway & Patrol Medical Plan is not expressly included in the new legislation, but section 104.801 RSMo. would require the Medical Plan to offer similar coverage.

However, 104.801 only requires similar coverage and the reporting requirements are not included in the mandates of 104.801. Currently, the Medical Plan does not cover costs for clinical trials. As a result, there would be a fiscal impact to the Highway & Patrol Medical Plan.

DHT assumes that if health carriers are required to cover the cost of services needed to administer the drugs or use the device under evaluation in the clinical trial, that manufacturers and distributors or providers of the drugs or devices would no longer pay for any of the related costs. Assuming that this is true, DHT assumes that the fiscal impact to the Medical Plan would be very significant.

Without knowing the types of drugs, procedures, illnesses or how many individuals would participate, DHT finds it is impossible to calculate what a fiscal impact to the Medical Plan would be.

FISCAL IMPACT - State Government	FY 2003	FY 2004	FY 2005
	(10 Mo.)		

ALL FUNDS

<u>Costs</u> - Missouri Consolidated Health

Care Plan

Increased state contributions (Unknown) (Unknown) (Unknown)

ESTIMATED NET EFFECT ON ALL FUNDS

(UNKNOWN) (UNKNOWN) (UNKNOWN)

CONSERVATION FUND

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FISCAL IMPACT - State Government	FY 2003 (10 Mo.)	FY 2004	FY 2005
<u>Costs</u> - Missouri Department of Conservation	()		
Increased state contributions	(Unknown)	(Unknown)	(Unknown)
ESTIMATED NET EFFECT ON CONSERVATION FUND	(UNKNOWN)	(UNKNOWN)	(UNKNOWN)
INSURANCE DEDICATED FUND			
Revenue - Department of Insurance Form filing fees	<u>\$9,850</u>	<u>\$0</u>	<u>\$0</u>
ESTIMATED NET EFFECT ON INSURANCE DEDICATED FUND	<u>\$9,850</u>	<u>\$0</u>	<u>\$0</u>
HIGHWAY FUND			
<u>Costs</u> - Department of Transportation Increased state contribution	(Unknown)	(Unknown)	(Unknown)
<u>Costs</u> - Department of Public Safety- Missouri State Highway Patrol Increased state contribution	(Unknown)	(Unknown)	(Unknown)
ESTIMATED NET EFFECT ON HIGHWAY FUND	(UNKNOWN)	(UNKNOWN)	(UNKNOWN)
FISCAL IMPACT - Local Government	FY 2003 (10 Mo.)	FY 2004	FY 2005
POLITICAL SUBDIVISION			
Cost - Political Subdivision Increased local contributions	(Unknown)	(Unknown)	(Unknown)
ESTIMATED NET EFFECT ON POLITICAL SUBDIVISIONS	(UNKNOWN)	(UNKNOWN)	(UNKNOWN)
FISCAL IMPACT - Small Business			

Small business could be affected by this proposal which could result in higher health insurance

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premiums.

DESCRIPTION

This proposal requires health insurance plans to provide coverage for routine patient care costs incurred as a result of participating in clinical trials for the prevention and treatment of cancer or the treatment of other life threatening illnesses. The clinical trial must be approved or funded by one of the entities which are specified in the proposal.

Entities seeking coverage of a clinical trial approved by an academic institutional review board in Missouri are required to maintain and electronically list clinical trials which meet the requirements of the proposal.

Providers participating in clinical trials are required to obtain a patient's informed consent which is consistent with current legal and ethical standards. Information required by this provision will be available to the health insurer upon request.

A policy, plan, or contract paid under Title 18 or Title 19 of the federal Social Security Act is exempt from the requirements of the proposal.

This legislation is not federally mandated, would not duplicate any other program and would not require additional capital improvements or rental space.

SOURCES OF INFORMATION

Department of Transportation
Department of Social Services
Missouri Consolidated Health Care Plan
Department of Insurance
Missouri Department of Conservation
Department of Public Safety Missouri State Highway Patrol

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Acting Director March 25, 2002